Amendments to the Drawings:

The attached sheet of drawings includes changes to FIG. 7a. This sheet, which includes Figs. 7a-7d, replaces the original sheet including FIGS. 7a-7d. In FIG. 7a, a duplicate reference numeral 730a has been corrected to reference numeral 730c.

Attachment: Replacement Sheet
Annotated Sheet

REMARKS/ARGUMENTS

Reconsideration of this application and entry of this Amendment are respectfully requested. Claims 4-7, 9-18, 22-26, and 28-33 are currently pending. Claims 12-18 were previously withdrawn. Claims 1-3, 8, 19-21, and 27 are canceled; claims 4-7, 10, 11, 22-26 and 29 are amended; and claims 30-33 added herein. New independent claims 30 and 32 effectively replace independent claims 1 and 19 respectively, and more clearly define the claimed elements of the elected invention. No new matter is added by this amendment. In view of the amendments and following remarks, favorable consideration and allowance of the application are respectfully requested.

35 U.S.C. §103 Rejections

Obviousness is a question of law, based on the factual inquiries of 1) determining the scope and content of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; and 3) resolving the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). *See* MPEP 2143.03. The applicant respectfully asserts that the cited references fail to teach or suggest all the claim limitations.

A. Claims 1-6, 10-11, 19-25, and 29 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,136,011 to Stambaugh (the *Stambaugh* patent) in view of U.S. Patent Publication No. 2002/0193820 to Wakuda, *et al.* (the *Wakuda* publication).

The applicant respectfully asserts that the *Stambaugh* patent and the *Wakuda* publication, alone or in combination, fail to disclose, teach, or suggest each and every element of the applicant's invention as claimed, as required to maintain a rejection under 35 U.S.C. §103(a). The applicant respectfully asserts that the *Stambaugh* patent and the *Wakuda* publication fail to disclose, teach, or suggest:

> a system for treating a vascular condition, comprising an elongate catheter body having an inflation lumen extending there through; an inflatable balloon disposed about the catheter body adjacent a distal end thereof, the balloon having

a deflated configuration wherein the balloon is compressed against an outer surface of the catheter body and an inflated configuration having a nominal balloon diameter; a first tubular restrictor having an unexpanded configuration disposed closely about the deflated balloon configuration and an expanded configuration adapted to substantially limit inflation of the balloon to a first restrictor diameter that is smaller than the nominal balloon diameter; a second tubular restrictor having an unexpanded configuration disposed closely about the unexpanded first restrictor configuration and an expanded configuration adapted to substantially limit inflation of the balloon to a second restrictor diameter that is smaller than the first restrictor diameter; and means coupled to a proximal end of the catheter body for inflating the balloon via the inflation lumen; wherein the first restrictor and the second restrictor are at least partially removable from the balloon such that when the balloon is fully inflated to an inflated diameter, the inflated balloon diameter is the second restrictor diameter when neither the first restrictor nor the second restrictor is removed, or the inflated balloon diameter is the first restrictor diameter when only the second restrictor is removed, or the inflatable balloon diameter is the nominal balloon diameter when both the first and second restrictors are removed, or

a balloon catheter comprising an elongate catheter body having an inflation lumen extending there through; an inflatable balloon disposed about the catheter body adjacent a distal end thereof, the balloon having a deflated configuration wherein the balloon is compressed against an outer surface of the catheter body and an inflated configuration having a nominal balloon diameter; a first tubular restrictor having an unexpanded configuration disposed closely about the deflated balloon configuration and an expanded configuration adapted to substantially limit inflation of the balloon to a first restrictor diameter that is smaller than the nominal balloon diameter; and a second tubular restrictor having an unexpanded configuration disposed closely about the unexpanded first restrictor configuration and an expanded configuration adapted to substantially limit inflation of the balloon to a second restrictor diameter that is smaller than the first restrictor diameter; wherein the first restrictor and the second restrictor are at least partially axially translatable from the balloon such that when the balloon is fully inflated to an inflated diameter, the inflated balloon diameter is the second restrictor diameter when neither the first restrictor nor the second restrictor is removed, or the inflated balloon diameter is the first restrictor diameter when only the second restrictor is removed, or the inflatable balloon diameter is the nominal balloon diameter when both the first and second restrictors are removed.

Neither the *Stambaugh* patent nor the *Wakuda* publication disclose a restrictor that is removable or axially translatable, or having a restrictor diameter limiting the inflation of the balloon to a diameter less than the nominal balloon diameter.

At most, the *Stambaugh* patent discloses two inflatable balloons fitted about a catheter near its distal end and positioned such that the relatively shorter inner balloon 30 is wholly contained within the relatively larger outer balloon 32. *See* column 3, lines 55-58. As seen in Figure 2 below, the inner balloon 30 and outer balloon 32 are fixed to the catheter 18 at the points indicated by the arrows.

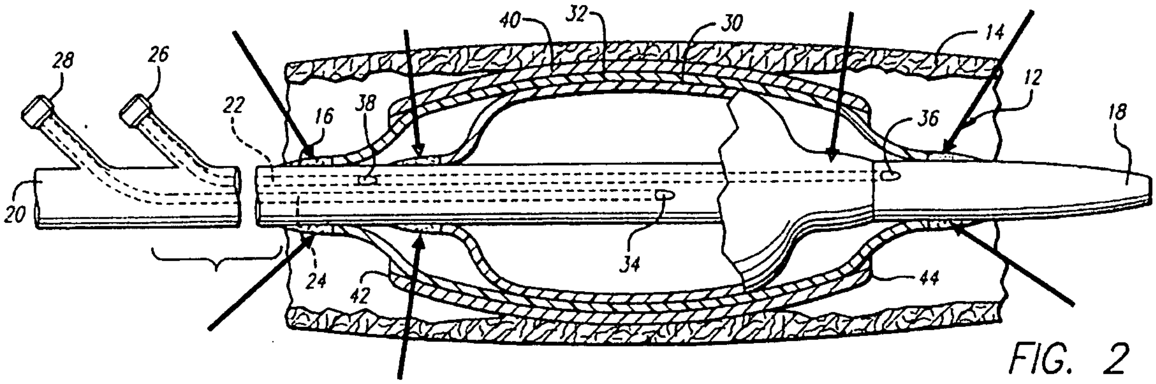


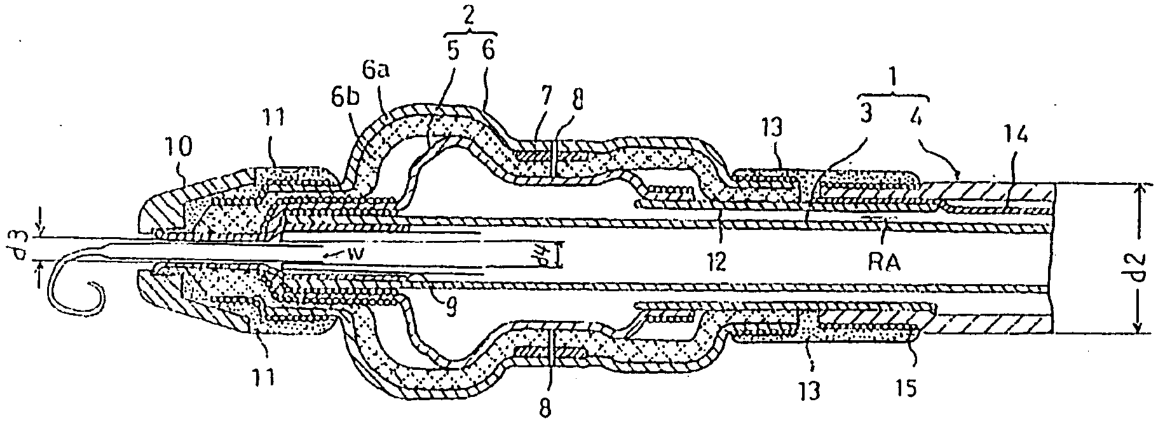
FIG. 2

Element 32 cited by the Examiner as a concentrically disposed restrictor is merely a balloon. Nothing in the *Stambaugh* patent suggests that the outer balloon 32 in any way restricts the inner balloon 30, so the *Stambaugh* patent fails to disclose a restrictor as now defined in independent claims 1 and 32. In fact, if the outer balloon 32 were a restrictor, the invention of the *Stambaugh* patent would be inoperable because the inner balloon 30 would not be able to urge the outer balloon 32 and the middle of stent 40 into the vessel wall of the body lumen 14. (FIG. 2 above and 4:12-17)

The outer balloon 32 and inner balloon 30 are fixedly attached to the catheter 18, so the *Stambaugh* patent fails to disclose first and second restrictors being removable or axially translatable as claimed. The existence of a deflate and inflate state as cited by the Examiner fails to make the balloons removable or axially translatable: The balloons remain mounted in the same relative position on the catheter whether deflated or inflated. (FIGS 1-4)

Even if the outer balloon 32 and inner balloon 30 were restrictors, which notion is disputed by applicant, the *Stambaugh* patent teaches away from adding additional layers to the two balloons. The *Stambaugh* patent states that the use of only two balloons rather than the three balloons employed in some previously known in systems not only enhances reliability but reduces manufacturing cost. The fact that the use of two balloons requires a lesser number of surfaces to be bonded and sealed to the catheter surface also enhances the reliability of the device. (2:57-62)

The *Wakuda* publication is cited by the Examiner as teaching a plurality of concentrically disposed concentric layers, but the *Wakuda* publication only discloses a double balloon device. At most, the *Wakuda* publication discloses a double balloon consisting of an inner balloon 5 to be inflated by means of an introduced fluid and an outer balloon 6 for receiving the inner balloon inflated with the introduced fluid as shown in FIG. 1 below.



The outer balloon 6 consists of an outer cylindrical elastic film 6a and an inner cylindrical sheath-core yarn fabric 6b for *reinforcing* the balloon, and the balloon-reinforcing sheath-core yarn fabric 6b is attached to the inner surface of the elastic film 6a using a rubber cement, etc., to prevent the scattering of the elastic film 6a and to assure uniform inflation without relative shifting even if the balloon is inflated and contracted. *See* paragraphs [0041], [0042]. Nothing in the *Wakuda* publication suggests that the outer balloon 6 restricts expansion of inner balloon 5. The elastic film of the inner balloon 5 is effectively reinforced by the outer balloon 6. *See* paragraph [0043]. Thus, the outer balloon 6 of the *Wakuda* publication is not a restrictor as now required in claims 30 and 32.

The *Wakuda* publication also fails to disclose first and second restrictors disposed one about the other, and both restrictors disposed about a balloon as now recited in the claim language of independent claims 30 and 32. At most, the *Wakuda* publication discloses the outer balloon 6 consists of an outer cylindrical elastic film 6a and an inner cylindrical sheath-core yarn fabric 6b for reinforcing the balloon, and the balloon-reinforcing sheath-core yarn fabric 6b is stuck to the inner surface of the elastic film 6a using a rubber cement the balloon-reinforcing sheath-core yarn fabric 6b, so the balloon-reinforcing sheath-core yarn fabric 6b and the inner surface of the elastic film 6a form a single unit, not a plurality of concentrically disposed restrictors as claimed. (FIG. 1; ¶0042)

In the present office action dated June 27, 2008, the Examiner asserts on page 3 that the concentrically disposed restrictor is "considered as another balloon type." The applicant respectfully disagrees. The restrictors of the present application are removable and/or axially translatable, making them inoperable as a balloon. The restrictors of the present application are disposed on the inflatable balloon in a manner that cannot in any way be considered to define independently sealed interior spaces that can receive inflation fluid and thereby inflate the restrictors as thought they were balloons.

Claims 4-6, 10, 11, and 22-25 and 29 depend directly or indirectly from independent claims 30 and 32, respectively, and so include all the elements and limitations of their respective independent claims. The applicant therefore respectfully submits that dependent claims 4-6, 10, 11, and 22-25 and 29 are allowable over the *Stambaugh* patent in view of the *Wakuda* publication for at least the same reasons as set forth above for their respective independent claims.

Regarding dependent claim 4, the *Stambaugh* patent and the *Wakuda* publication fail to disclose the first restrictor and the second restrictor are partially removable to control an expandable length of the inflatable balloon.

Regarding dependent claims 5 and 23, the *Stambaugh* patent and the *Wakuda* publication fail to disclose a first restrictor being frictionally coupled to the inflatable balloon and a second restrictor being frictionally coupled to the first restrictor. In particular, *Wakuda* discloses that inner balloon 5 is coated with silicone grease. (¶0042) The applicant was unable to locate any discussion in the outstanding Office Action where the Examiner identified where either the *Stambaugh* patent or the *Wakuda* publication disclose the requirements of claims 5 and 23.

Regarding dependent claim 22, the *Stambaugh* patent and the *Wakuda* publication fail to disclose the first restrictor and the second restrictor are axially translatable to control an expandable length of the inflatable balloon.

Claims 1-3, 8 and 19-21 have been canceled, rendering the rejection of these claims moot. Withdrawal of the rejection of claims 4-6, 10, 11, 22-25 and 29 under 35 U.S.C. §103(a) as being unpatentable over the *Stambaugh* patent in view of the *Wakuda* publication is respectfully requested.

B. Claims 7-9 and 26-28 have been rejected under 35 U.S.C. §103(a) as being unpatentable over the *Stambaugh* patent in view of the *Wakuda* publication, and further in view of U.S. Patent No. 5,338,298 to McIntyre (the *McIntyre* patent).

The applicant respectfully asserts that the *Stambaugh* patent, the *Wakuda* publication, and the *McIntyre* patent, alone or in combination, fail to disclose, teach or suggest each and every element of the applicant's invention as claimed, as required to maintain a rejection under 35 U.S.C. §103(a). As discussed in Section A above, the applicant asserts that the *Stambaugh* patent and the *Wakuda* publication fails to disclose, teach, or suggest:

> a system for treating a vascular condition, comprising an elongate catheter body having an inflation lumen extending there through; an inflatable balloon disposed about the catheter body adjacent a distal end thereof, the balloon having a deflated configuration wherein the balloon is compressed against an outer surface of the catheter body and an inflated configuration having a nominal balloon diameter; a first tubular restrictor having an unexpanded configuration disposed closely about the deflated balloon configuration and an expanded configuration adapted to substantially limit inflation of the balloon to a first restrictor diameter that is smaller than the nominal balloon diameter; a second tubular restrictor having an unexpanded configuration disposed closely about the unexpanded first restrictor configuration and an expanded configuration adapted

to substantially limit inflation of the balloon to a second restrictor diameter that is smaller than the first restrictor diameter; and means coupled to a proximal end of the catheter body for inflating the balloon via the inflation lumen; wherein the first restrictor and the second restrictor are at least partially removable from the balloon such that when the balloon is fully inflated to an inflated diameter, the inflated balloon diameter is the second restrictor diameter when neither the first restrictor nor the second restrictor is removed, or the inflated balloon diameter is the first restrictor diameter when only the second restrictor is removed, or the inflatable balloon diameter is the nominal balloon diameter when both the first and second restrictors are removed, or

a balloon catheter comprising an elongate catheter body having an inflation lumen extending there through; an inflatable balloon disposed about the catheter body adjacent a distal end thereof, the balloon having a deflated configuration wherein the balloon is compressed against an outer surface of the catheter body and an inflated configuration having a nominal balloon diameter; a first tubular restrictor having an unexpanded configuration disposed closely about the deflated balloon configuration and an expanded configuration adapted to substantially limit inflation of the balloon to a first restrictor diameter that is smaller than the nominal balloon diameter; and a second tubular restrictor having an unexpanded configuration disposed closely about the unexpanded first restrictor configuration and an expanded configuration adapted to substantially limit inflation of the balloon to a second restrictor diameter that is smaller than the first restrictor diameter; wherein the first restrictor and the second restrictor are at least partially axially translatable from the balloon such that when the balloon is fully inflated to an inflated diameter, the inflated balloon diameter is the second restrictor diameter when neither the first restrictor nor the second restrictor is removed, or the inflated balloon diameter is the first restrictor diameter when only the second restrictor is removed, or the inflatable balloon diameter is the nominal balloon diameter when both the first and second restrictors are removed.

The *McIntyre* patent also fails to disclose these elements. Claims 7 and 9 and claims 26 and 28 depend directly or indirectly from independent claims 30 and 32, respectively, and so include all the elements and limitations of their respective independent claims. The applicant therefore respectfully submits that dependent claims 7, 9, 26 and 28 are allowable over the *Stambaugh* patent in view of the *Wakuda* publication in further view of the *McIntyre* patent for at least the same reasons as set forth above for their respective independent claims.

Regarding claims 7 and 26, the *McIntyre* patent fails to disclose a restrictor removal element attached to each restrictor. At most, the *McIntyre* patent discloses a cylindrical proximal neck or collar 28 for adhesively attaching the balloon 16 to the catheter shaft 10. (FIGS 1-3; 2:47-53) The cylindrical proximal collar 28 is merely a balloon attachment and has nothing to do with a restrictor or a restrictor removal element. As stated in the present application, a restrictor removal element can be attached to each restrictor. *See* paragraphs [0036], [0043], [0056], [0063], and [0073] of the present specification.

Regarding claims 9 and 28, the *McIntyre* patent fails to disclose the restrictor removal element as a tab, a flap, a string, a thread, or a wire.

Withdrawal of the rejection of claims 7, 9, 26 and 28 under 35 U.S.C. §103(a) as being unpatentable over the *Stambaugh* patent in view of the *Wakuda* publication in further view of the *McIntyre* patent is respectfully requested.

New Claims

Claims 30-33 have been added herein to more particularly point out and distinctly claim the applicant's invention. As mentioned above, new independent claims 30 and 32 effectively replace independent claims 1 and 19 respectively, and more clearly define the claimed elements of the elected invention. No new matter has been added with the inclusion of claims 30-33, which are supported in the specification at least on pages 10-20.

Conclusion

For the foregoing reasons, applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to

Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (978) 739-3075 (Eastern Time).

Respectfully submitted,

/James F. Crittenden/
James F. Crittenden
Registration No. 39,560
Agent for Applicant

Medtronic Vascular, Inc.
3576 Unocal Place
Santa Rosa, CA 95403
Facsimile No.: (707) 543-5420

APPENDIX

Annotated Sheet

FIG. 7a

700

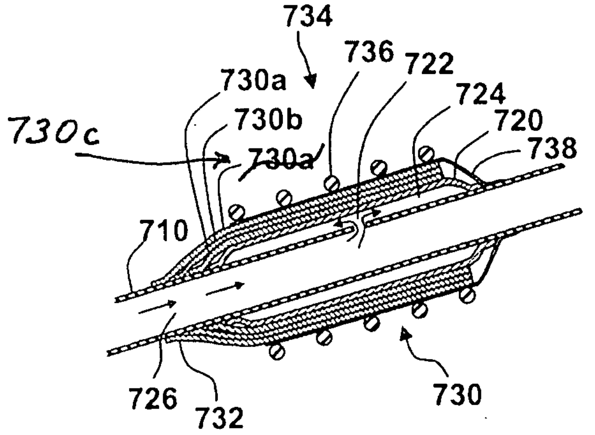


FIG. 7b

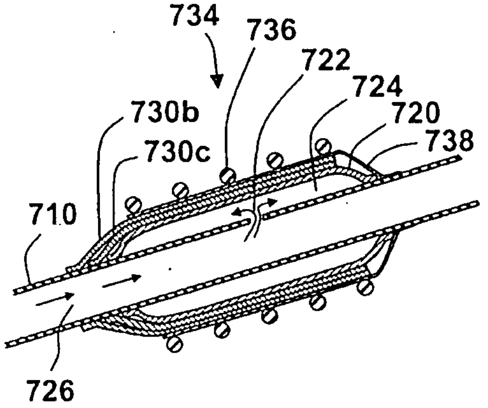


FIG. 7c

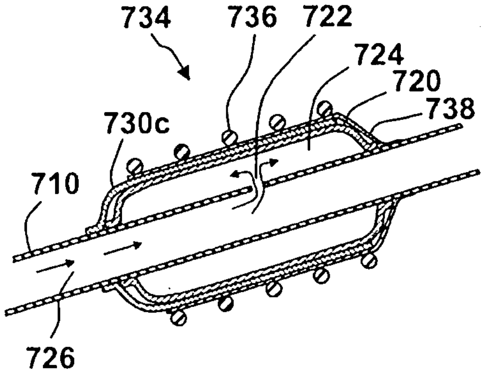


FIG. 7d